Title:

Inguinal Hernia Repair Prosthesis

This invention relates to an implantable prosthesis intended, primarily for the repair of muscle wall defects such as occur in inguinal hernias.

Prosthetic mesh materials are known for the repair and reinforcement of muscle walls. In one technique the mesh is formed into a conical shape forming a plug which is inserted in the hernia defect, often with placement of an additional sheet of flat mesh, to close the defect. In another form, shown in EP 0614650, there is disclosed a conical plug of a mesh material configured with pleats and having inserted petal-like parts. This is stated to have an improved closure performance. The known devices are all useful for, and concerned with, closure of generally localised, or circular plan defects and it has been found that difficulties may occur when the defect opening has a more longitudinal dimension, as is seen with a direct inguinal hernia defect in particular. Here, one or more conical or circular plan plugs is potentially unsatisfactory.

It is one object of this invention to provide an implantable prosthesis which performs to an enhanced degree for inguinal hernias having a more rectangular or elongate opening and in particular, for direct hernias..

According to this invention there is provided an implantable prosthesis for the repair of muscle wall defects such as occur in inguinal hernias, the prosthesis comprising a flexible plug of a surgically compatible mesh material, *characterised in that* the plug has an elongate form with one portion at least of the surface of the plug forming a projecting longitudinal ridge or bulge.

In a advantageous shape a portion of the surface of the plug may

comprise a projecting lobe formed by, or on, the surface. In a preferred arrangement the plug has a prismatic shape with a generally triangular cross-section.

In a preferred prosthesis according to this invention the cross-section of the plug has a three lobed profile. The apices of the lobes may be joined by linear sides, providing a generally triangular cross-section. More than three lobes, or ridges, may be provided.

With a construction of this kind it has been found, surprisingly, that closure of elongate legions is readily achieved and the plug serves for closure of a wide range of elongate shapes and dimensions of hernias.

The elongate mesh material forming the plug preferably has internal longitudinal support webs to support the profile of the mesh. These webs may be an integral part of the mesh configured by folding or formed by separate parts bonded to the inner surface of the outer profile. In another construction three, or more, elongate sub-units may be connected to form the complete prosthesis. Such sub-units may themselves be of a triangular profile.

The wall of the mesh may be pleated circumferentially, or longitudinally to provide a degree of flexibility and compressibility, to facilitate placement into the defect comprising the hernia. For each requirement the mesh plug can be cut to an appropriate required dimension from a stock length piece. This is in contrast to known prostheses which are of pre-determined dimensions whose size, for placement, must be judged carefully by the operating surgeon.

In an alternative construction the plug comprises a plurality of individual units connected in a longitudinal side-by-side relationship. Such units may individually have a prismatic profile.

This invention also embraces a construction wherein the plug has an open side being in the form of a triangular profiled trough, the shape then being maintained by internal support formed by mesh material.

Hitherto, a size mis-match issue has proved difficult to resolve with known plugs and the use of two or more plugs is expensive and can lead to unnecessary manipulation during the closure process, Hernia recurrence might occur. The present invention avoids such a basic problem and may be used with elongate and rectangular openings such as found, in particular, with direct inguinal hernia defects to which known plugs may provide an unsatisfactory repair.

The mesh material may be polypropylene and any jointing required may be achieved, for example, by heat sealing. Materials and techniques for the manufacture of surgical mesh materials of the kind useful in carrying out this invention are well known in the art and are not therefore further described in any more detail.

Embodiments according to this invention are described in more detail with reference to examples illustrated in the drawings. In the drawings:

Fig. 1 shows a first embodiment of a prosthesis with internal web support and according to this invention,

Fig. 2 shows a second embodiment of prosthesis made from sub-units,

Fig. 3 shows a third embodiment of prosthesis with internal support, and

Fig. 4 shows a fourth embodiment with a further internal support.

Referring to Fig. 1, an implantable prosthesis intended, primarily for the repair of muscle wall defects such as occur in inguinal hernias is fabricated from a surgically compatible mesh material having a prismatic external mesh

wall 1. The prismatic shape includes three lobes 2, providing a generally triangular cross-sectional shape. The shape is maintained by internal reinforcing ribs 3, which here extend the length of the prism, although discrete spaced ribs may be provided for certain applications. The ribs are formed through the connection of three individual mesh strips 4, with each rib comprising two strip parts forming a lamination extending the length of the prism.

Fig. 2 shows a second embodiment according to this invention wherein the prism 20 is formed from three sub-units 21 (shown separated here), with each sub-unit 21 having a triangular shape in cross-section. The sub-units 21 are joined by suitable and known techniques to form the complete prosthesis.

The embodiment shown in Fig. 3, is a variation of that shown in Fig. 1 where the internal supporting ribs comprise two back-to-back L-shaped supports, with the base limbs 31 lying on the lower internal side of the prism and the vertical limbs 30 extending together to the upper lobe 32. Lateral reinforcement 33 may be provided.

Fig. 4 shows a construction similar to Fig. 3 but here the base limbs 31 of the two L-shaped supports 30 extend around the internal profile of the opposed lobes 33 and 34.

In all the embodiments, and according to a feature of this invention, the mesh material may be ridged, pleated, crumpled, or folded to stiffen or pad out the prosthesis this being with particular reference to the internal supports or webs.

In each case, the plug device is intended, primarily for placement into (direct) inguinal hernia defects. From stock lengths, the device can be cut

exactly to the correct size. The plug can be sutured into place, or tissues sutured over to hold it in place. The plug may be used with a second, flat, overlying piece of mesh to thus form a tension-free repair.

In contrast to known conical plug devices which, when used together, have gaps between the apices allowing gut penetration, the present invention provides a single elongate plug which can be cut to size thus providing better closure and more resistance to penetration by the gut.